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EXAMINER	
YOO, REGINA M	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/685,545	**Applicant(s)** CANNADY ET AL.	
	Examiner REGINA YOO	**Art Unit** 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2008*.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-17,37-39,41,43-48,54 and 55* is/are pending in the application.
  4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-4, 7-17, 37-39, 41, 43-48, 54-55* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  a)☐ All b)☐ Some * c)☐ None of:
    1.☐ Certified copies of the priority documents have been received.
    2.☐ Certified copies of the priority documents have been received in Application No. _____.
    3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
  * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
  Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
  Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

Response to Amendment

The amendment filed on 5/05/2008 has been received and claims 1-4, 7-17, 37-39, 41, 43-48 and 54-55 are pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

   1. Determining the scope and contents of the prior art.
   2. Ascertaining the differences between the prior art and the claims at issue.
   3. Resolving the level of ordinary skill in the pertinent art.
   4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 4, 7-9, 11, 37 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosano (3780857) in view of Davis (6440375).

As to Claims 1, 4, 7-8, 37 and 54, Rosano (‘857) discloses a sterilization wrap (10) (see entire document, particularly Figures 2-6) for enabling one to wrap an article (33) to be sterilized, comprising:

at least one sheet of sterilization material (18); said sheet (18) of sterilization material being a multi-ply laminate (see entire document, particularly Col. 1, lines 5-8 and 49-53 where the laminated material is deemed to be multi-ply configuration as the one layer is encapsulated/laminated on top and bottom by laminating material/layer);

an additional sheet (11) of absorbent material attached to said sheet (18) of sterilization material (see Col. 1, lines 17-18 and 54-56);

- said additional sheet (11) of absorbent material bonded to said sheet of sterilization material (18) (see Col. 1, line 18) adapted to contact the article (33) to be sterilized (see Figure 6);
- said additional sheet (11) being bonded to the central portion of said first sheet (18) (see Figure 6 and Col. 1, lines 54-56); the perimeter of said additional sheet (11) being at least twenty-five percent smaller than the perimeter of said first sheet (18) (see Col. 1, lines 58-63; where the perimeter of the additional sheet 11 is 28 inches and the perimeter of the first sheet 18 being 64 inches, so the perimeter of the additional sheet is about 56% smaller than the first sheet perimeter); and
- said additional sheet of absorbent material (a) providing sterility protection for the article (33) in addition to said sheet (18) of sterilization material (as the cardboard provides a base to support the articles in place of traditional sterilization trays made of stainless steel which prevents the articles from puncturing/damaging the wrap material that will compromise the sterility achieved within – see Col. 1, lines 2-6 and 16-18), and (b) enabled to wick moisture away from the article (33) after sterilization has

taken place (wherein the absorbent material is cardboard which is intrinsically moisture absorbent).

Rosano (‘857) does not appear to specifically teach that the additional absorbent sheet material is non-rigid nor that said additional sheet of absorbent material is constructed so as to permit sterilant to readily pass therethrough.

It was well known in the art at the time of invention to provide a non-rigid, absorbent sheet material that is placed under the article to be sterilized in a sterilization wrap system and constructed so as to absorb moisture and permit sterilant to readily pass therethrough in a sterilization wrap. Davis (‘375) exemplifies a sterilization wrap system for wrapping an article (30) to be sterilized (see entire document, particularly Figure 2), comprising:

at least a first sheet of sterilization material (40); said first sheet having an outer periphery and a central portion (see Figure 2); and

an additional sheet of absorbent material (10) placed on said first sheet of sterilization material (40);

- said sheet of absorbent material (10) adapted to receive the article (30) to be sterilized thereon; said sheet of absorbent material (10) (a) providing sterility protection for the article (30) in addition to said first sheet of sterilization material (40) (where the additional sheet of the absorbent material prevents tear in the first sheet so as to prevent compromising the sterility of the articles within; see entire document, particularly Col. 5 lines 1-5), and (b) wicking moisture away from the article (30, 20) after sterilization has taken place (see entire document, particularly Col. 6 lines 42-47),

- said sheet of absorbent material (10) being non-rigid (where the sheet (10) of super-absorbent material made from an absorbent synthetic material in the form of hydrophilic polyurethane foam - see Col. 3 lines 8-12 - is a known non-rigid absorbent material), contacts the article to be sterilized (30) (see Figures 1-2), and permits sterilant to readily pass therethrough (see entire document, particularly Col. 6 lines 48-54),

in order to advantageously cushion article(s) to be sterilized both during and after a sterilization process as well as to prevent residual moisture on instrument surfaces post-sterilization, and allow effective operation of conventional sterilization processes with sterilant such as steam and ethylene oxide (see entire document, particularly Col. 3 lines 3-8 and 47-51).

It would have been obvious to one of ordinary skill in this art at the time of invention to provide a non-rigid sheet of absorbent material in the sterilization wrap of Rosano in order to promote wicking of moisture away from the article to be sterilized after sterilization and to cushion/protect the article so as to prevent tear of the sterilization sheet material by the article as exemplified by Davis.

As to Claims 9 and 11, Rosano (‘857) discloses that the first sheet of sterilization material (18) has two sides (see Figures 2-6, particularly Figure 5 where there is an interior side that contains the articles and 11 and the exterior side as seen in Figure 2); one side of said first sheet of sterilization material (18) having a central portion (as defined by 13 and 21); said sheet of absorbent material bonded to said first sheet of sterilization material at said central portion adhesively (see Figure 6 and Col. 1, lines 18 and 54-55 wherein “adhesively secured” is deemed to include bonding by glue).

Thus, Claims 1, 7-9, 11, 37 and 54 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Rosano (‘857) and Davis (‘375).

4. Claims 2-3, 10, 12-13, 38-39 and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosano (3780857) in view of Davis (6440375) as applied to claims 1 and 37 above, and further in view of Bourne (5688476).

Rosano (‘857) and Davis (‘375) are relied upon for disclosure described in the rejection of claims 1 and 37 under 35 U.S.C. 103(a).

As to claims 2-3, 10, 12, 38-39 and 46, while Rosano (‘857) discloses that the wrap comprises of a first sterilization sheet made from non-woven, laminate material (see Col. 1, lines 48-52), Rosano (‘857) does not appear to specifically teach that the wrap further includes a second sheet of sterilization material; said second sheet of sterilization material being bonded to said first sheet of sterilization material; where the second sheet of sterilization material includes an outer periphery with four edges; said outer periphery of said first sheet of sterilization material having four edges being bonded to said outer periphery of said second sheet of sterilization material by heat and pressure; nor that the first and second sheets of sterilization material are made of SMS.

It was known in the art at the time of invention to provide two sheets of sterilization material for wrapping an article for sterilization where the two sheets are made of SMS and bonded to each other along the outer periphery of the sheets. Bourne ('476) discloses a sterilization wrap (10) for enabling one to wrap an article (18) to be sterilized, comprising:

a first sheet of sterilization material (12); said first sheet (12) having an outer periphery with four edges about the periphery and a central portion (see Figures 1-6); and

a second sheet of sterilization material (14); said second sheet (14) having an outer periphery with four edges about the periphery and a central portion (see Figures 1-6);

wherein the two sheets are made of SMS in order to provide properties such as strength and barrier properties to the wrap (see Col. 7, line 29 through Col. 8, line 9, and Col. 9, lines 33-48 and 55-65) and the outer periphery of the first sheet (12) is bonded to said outer periphery of the second sheet (14) by heat and pressure (see Col. 5, lines 22-23 and 26-29) in order to join the two sheets of the sterilization material together (see Figures 4-6, particularly Figure 6 and Col. 5 line 48 through Col. 6 line 19).

It would have been obvious to one of ordinary skill in this art at the time of invention to provide two sheets of sterilization material for wrapping an article for sterilization where the two sheets are made of SMS and bonded to each other along the outer periphery of the sheets in the sterilization wrap of Rosano in order to provide strength and barrier properties to the wrap and to join the two sheet together as shown by Bourne.

As to Claim 13, while Rosano ('857) discloses that the sterilization wrap is comprised of two sheets - a first sheet and an absorbent sheet, Rosano ('857) does not appear to specifically teach that the two materials have different colors so that a sterile field may be readily identified.

Bourne ('476) discloses that the sterilization wrap (10) has two sheets (12, 14) wherein the shading or coloring of the inner sheet 14 is different than the outer sheet 12 in order to visually distinguish and properly position the wrap 10 so that the correct inner sheet of the wrap faces the item to be wrapped (see Col. 8, lines 46-61).

It was known in the art at the time of invention to provide different coloration to the different sheets of a sterilization wrap and it would have been obvious to one of ordinary skill in this art at the time of invention to provide such different coloration/shading of the sheets in the wrap of Rosano in order to visual distinguish the two surfaces for proper orientation of the wrap with the article to be sterilized as shown by Bourne.

As to Claims 47-48, while Bourne ('476) discloses that the basis weight of the first sheet of sterilization material is 1.05 to 3.57 osy (see Table I and Col. 9, line 33 through Col. 10, line 16), neither Rosano (‘857) nor Davis (‘375) appears to specifically teach the basis weight of the absorbent sheet is in the range from 1.0 osy to 3.0 osy such that the basis weight of said additional sheet is greater than the basis weight of said first sheet of sterilization material.

It was well known in the art at the time of invention to manufacture an absorbent sheet material in the form of foam having various basis weights. It would have been well within the purview of one of ordinary skill in the art to utilize a polyurethane foam sheet material with basis weight in the range from 1.0 osy to 3.0 osy such that the basis weight of said additional absorbent sheet is greater than the basis weight of said first sheet of sterilization material in the sterilization wrap system of Rosano as modified by Davis in order to provide an absorbent material that is suitably optimized for the sterilization system to wick moisture as well as to cushion articles for sterilization. Only the expected results would be attained.

Thus, Claims 2-3, 10, 12-13, 38-39 and 46-48 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Rosano (‘857), Davis (‘375) and Bourne (‘476).

5. Claims 14-15, 17, 41, 43-45 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosano (3780857) in view of Davis (6440375) as applied to claims 1, 37 and 54 above, and further in view of Thukamoto (4206844).

Rosano (‘857) and Davis (‘375) are relied upon for disclosure described in the rejection of claims 1, 37 and 54 under 35 U.S.C. 103(a).

As to Claims 14, 41, 43 and 55, while both Rosano (‘857) and Davis (‘375) teaches a sterilization wrap, neither Rosano (‘857) nor Davis (‘375) appears to specifically teach that the sterilization wrap further includes a chemical visual indicator responsive to the presence of sterilant so as to indicate whether or not the article has been exposed to adequate sterilization conditions.

It was well known in the art at the time of invention to include a chemical visual indicator within a package formed using a sterilization wrap material. Thukamoto (‘844) exemplifies sterilization wraps (1 and 2) for wrapping an article (3) to be sterilized (Abstract) further including a chemical visual indicator (5); said chemical visual indicator (5) being in one visual state/color prior to exposure to sterilant and being in another visual state/color after exposure to sterilant (Col. 4, lines 22-26; Col. 5, lines 6-11); said chemical visual indicator being attached to said wrap (see Figure 1-3, 5) so as to indicate whether or not the article has been exposed to adequate sterilization conditions (Col. 4, lines 22-26).

It would have been obvious to one of ordinary skill in this art at the time of invention to provide a chemical visual indicator in the sterilization wrap system of Rosano as modified by Davis in order to obtain a means to ascertain “the completion of disinfection of a medical instrument received” with ease (Col. 4, lines 22-26) as shown by Thukamoto.

As to Claims 17 and 44, while Thukamoto (‘844) does not appear to specifically teach that the chemical visual indicator meets the requirements of ISO 11140-1, it would have been obvious to one of ordinary skill in this art at the time of invention to use a chemical visual indicator that meets such a requirement in a sterilization wrap system of Rosano as modified by Davis and Thukamoto in order to demonstrate that the indicator and ultimately the sterilization wrap system achieves industry acceptable/standard level of performance.

As to Claims 15 and 45, while neither Rosano (‘857) nor Davis (‘375) teaches that a chemical visual indicator is attached to said additional sheet, Thukamoto (‘844) discloses that the chemical visual indicator (5) is located on a sheet (1) where the article (3) to be sterilized is placed (see Figure 2) in order to enable visual recognition of the completion of sterilization/disinfection at the location of the sterilized article (see Abstract). Thus, it would have been obvious to one of ordinary skill in this art at the time of invention to attach the chemical visual indicator also on the additional sheet of Rosano as modified by Davis upon which the items for sterilization are placed in order to ensure that the interior of the sterilization wrap where the article to be sterilized is located has received sterilant to effect sterilization as shown by Thukamoto.

Thus, Claims 14-15, 17, 41, 43-45 and 55 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Rosano (‘857), Davis (‘375) and Thukamoto (‘844).

6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosano (3780857) and Davis (6440375) in view of Thukamoto (4206844) as applied to claim 14 above, and further in view of Romito (4382063).

Rosano (‘857), Davis (‘375) and Thukamoto (‘844) are relied upon for disclosure described in the rejection of claim 14 under 35 U.S.C. 103(a).

While Thukamoto (‘844) teaches that the chemical visual indicator changes color after having been exposed to a sterilant gas, Thukamoto (‘844) does not appear to teach that the chemical visual indicator changes color after having been exposed to steam.

It was well known in the art at the time of invention to provide a chemical visual indicator that changes color after exposure to steam in a sterilization system. Romito (‘063) exemplifies a chemical visual indicator that changes color after having been exposed to steam (Abstract). It would have been obvious to one of ordinary skill in this art at the time of invention to provide the chemical visual indicator for steam sterilization instead of the chemical visual indicator of Thukamoto in the sterilization system of Rosano (‘857) as modified by Davis in order to provide an indicator for a steam sterilization application so as to “visually show that steam sterilization has been completed” (Col. 1, lines 6-7) as exemplified by Romito.

Thus, Claim 16 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Rosano (‘857), Davis (‘375), Thukamoto (‘844) and Romito (‘063).

Response to Arguments

7. Applicant's arguments filed 5/05/2008 have been fully considered but they are not persuasive.

8. Specifically, as to Applicant's argument that the trayliner 10 of Davis "is not adapted to receive or contact the instruments 20 or provide sterility protection for the instruments 20", Examiner would point out that the trayliner 10 of Davis is adapted to receive or contact the instruments 20 as shown in Figures 1-2 and that the same trayliner 10 is utilized also to support the tray, which is deemed to be the article to be sterilized for the purposes of the claim rejection. As Applicant has not particularly specified that the article to be sterilized is in the form of instruments, Examiner notes that the feature upon which applicant relies (as discussed) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993)).

Applicant further argues that "Davis does not specifically teach that the trayliner 10 is bonded to the sterilization wrap". However, Examiner would point out that Applicant is arguing against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Specifically, the limitation of the absorbent sheet being bonded to the first sheet of sterilization material has been met by the reference of Rosano.

As to Applicant's argument that "it is not clear whether it is possible to bond the polyurethane foam trayliner 10 of Davis to a multiply laminate…since Davis merely teaches that the trayliner 10 is placed between the tray 30 and the paper sterilization wrap 10", Examiner would point out that there is no specific teaching that limits or prohibits the trayliner from being bonded (i.e. bonding of the polyurethane to another substrate). Thus, Examiner would continue to maintain that it would have been obvious to bond the trayliner 10 of Davis to the multiply laminate sterilization material of Rosano. Furthermore, Examiner would take the position that it would have been obvious and well within the purview of one of ordinary skill in the art to bond the trayliner of Davis to the multiply laminate sterilization sheet in a manner such as placing bonding points/sites along the outermost periphery of the trayliner with the sterilization material to maintain/retain the properties of wicking away moisture and permeability to a sterilant after such bonding. Only the expected results would be attained.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REGINA YOO whose telephone number is (571)272-6690. The examiner can normally be reached on Monday-Friday, 10:00 am - 7:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RY

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797